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(54) **EXTENSION FOR ILIAC BRANCH DELIVERY DEVICE AND METHODS OF USING THE SAME**

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(51) **Int. Cl.**

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A61F 2/966	(2013.01)
A61F 2/07	(2013.01)
A61F 2/06	(2013.01)

(52) **U.S. Cl.**

CPC ***A61F 2/954*** (2013.01); ***A61F 2/966*** (2013.01); *A61F 2/07* (2013.01); *A61F 2002/061* (2013.01); *A61F 2002/067* (2013.01)

(58) **Field of Classification Search**

CPC A61F 2/00736; A61F 2/009; A61F 2009/00874; A61F 2009/00887; A61F 2002/067; A61F 2002/061; A61F 2/966; A61F 2/954; A61F 2/07

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,383,852	A	1/1995	Stevens-Wright	
5,429,617	A	7/1995	Hammersmark et al.	
5,676,697	A *	10/1997	McDonald	A61F 2/90 623/1.35
5,746,766	A	5/1998	Edoga	606/198
5,921,978	A	7/1999	Thompson et al.	
6,285,903	B1	9/2001	Rosenthal et al.	
6,520,934	B1	2/2003	Lee et al.	
6,695,875	B2	2/2004	Stelter et al.	623/1.13
6,827,726	B2	12/2004	Parodi	
6,849,087	B1	2/2005	Chuter	623/1.23
7,108,715	B2	9/2006	Lawrence-Brown et al.	623/1.21
7,344,556	B2	3/2008	Seguin et al.	
7,393,357	B2	7/2008	Stelter et al.	623/1.11
7,815,608	B2	10/2010	Schafersman et al.	604/164.01
7,867,270	B2	1/2011	Hartley et al.	623/1.11
7,930,014	B2	4/2011	Huennekens et al.	

(Continued)

FOREIGN PATENT DOCUMENTS

WO	WO 99/47078 A1	9/1999
WO	WO 01/67993 A2	9/2001

(Continued)

OTHER PUBLICATIONS

International Search Report and Written Opinion for PCT/US2011/029037, dated Jul. 21, 2011, 10 pages.

(Continued)

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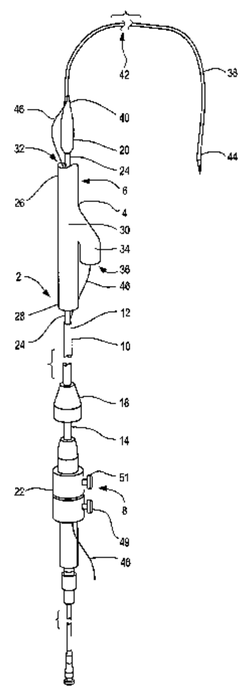
(57) **ABSTRACT**

Methods for accessing the common and internal iliac arteries and delivering and deploying an endovascular graft therein are disclosed. A system including a pre-loaded delivery and deployment device with an extension sheath is described which enables such a method to be practiced is also disclosed.

16 Claims, 13 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

7,998,186	B2	8/2011	Hartley	623/1.11
8,012,193	B2	9/2011	Hartley et al.	623/1.11
8,014,849	B2	9/2011	Peckham	
8,043,354	B2	10/2011	Greenberg et al.	
8,118,854	B2	2/2012	Bowe	
8,262,718	B2	9/2012	Chuter et al.	623/1.11
2005/0159773	A1	7/2005	Broome et al.	
2005/0255317	A1	11/2005	Bavaro et al.	
2007/0083215	A1	4/2007	Hamer et al.	606/108
2007/0123910	A1	5/2007	Hartley et al.	606/108
2007/0250154	A1	10/2007	Greenberg et al.	623/1.13
2008/0221656	A1	9/2008	Hartley et al.	623/1.11
2010/0016943	A1	1/2010	Chobotov	
2011/0270375	A1	11/2011	Hartley et al.	623/1.11
2011/0270376	A1	11/2011	Hartley	623/1.11
2011/0295111	A1	12/2011	Hansis et al.	
2012/0172968	A1	7/2012	Chuter et al.	623/1.12
2013/0030514	A1	1/2013	Kasprzak et al.	623/1.12
2013/0204342	A1	8/2013	Kasprzak et al.	

FOREIGN PATENT DOCUMENTS

WO	WO 2004/047885	A2	6/2004
WO	WO 2004/089249	A1	10/2004
WO	WO 2005/037141	A2	4/2005
WO	WO 2007/124053	A1	11/2007
WO	WO 2010/127040		11/2010
WO	WO 2010/127040	A1	11/2010
WO	WO 2011/116308		9/2011

OTHER PUBLICATIONS

International Preliminary Report on Patentability for PCT/US2011/029037, dated Mar. 22, 2012, 6 pages.

Response to International Search Report and Written Opinion, dated Jan. 19, 2012, 11 pages.

International Patent Examination Report No. 1 for Australian Patent Application No. 2012200735 dated Jun. 20, 2012, 8 pages.

Office Action/Restriction received in related U.S. Appl. No. 13/635,573 dated May 2, 2013, 7 pages.

Response to Office Action/Restriction filed in related U.S. Appl. No. 13/635,573 dated May 9, 2013, 12 pages.

Office Action received in related U.S. Appl. No. 13/635,573 dated Aug. 6, 2013, 13 pages.

Response to Office Action filed in related U.S. Appl. No. 13/635,573 dated Aug. 15, 2013, 14 pages.

Notice of Allowance received in related U.S. Appl. No. 13/635,573 dated Oct. 29, 2013, 11 pages.

Extended International Search Report for European Patent Application No. EP 14275023, dated Jun. 2, 2014, 6 pages.

Extended European Search Report for corresponding EP 16275039 dated Jun. 17, 2016, 8 pages.

* cited by examiner

Fig. 1

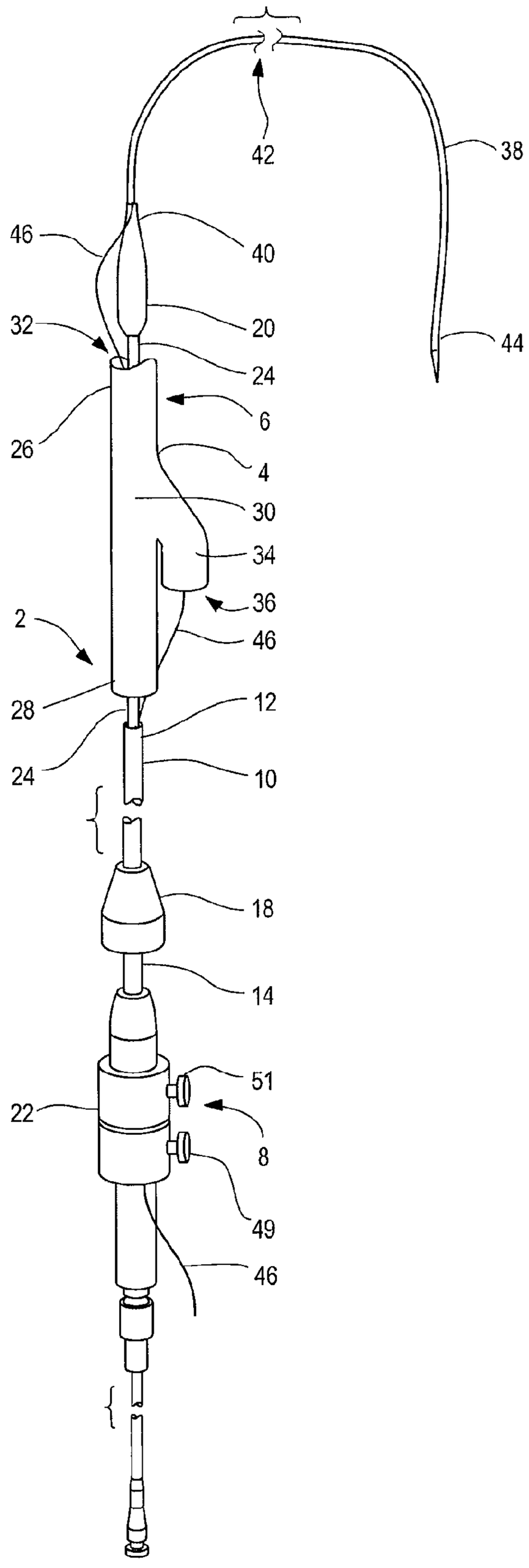

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Fig. 2

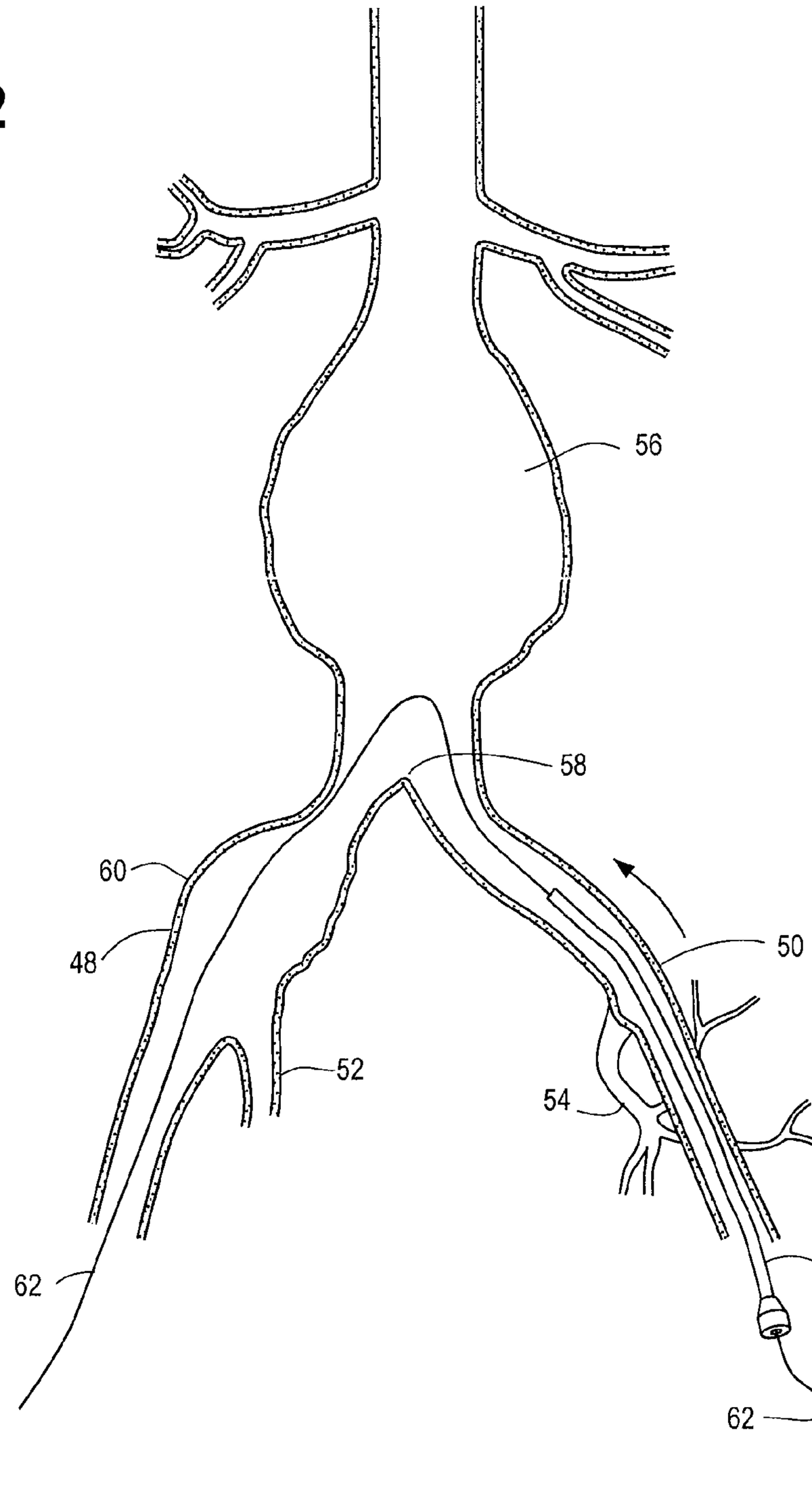


Fig. 3

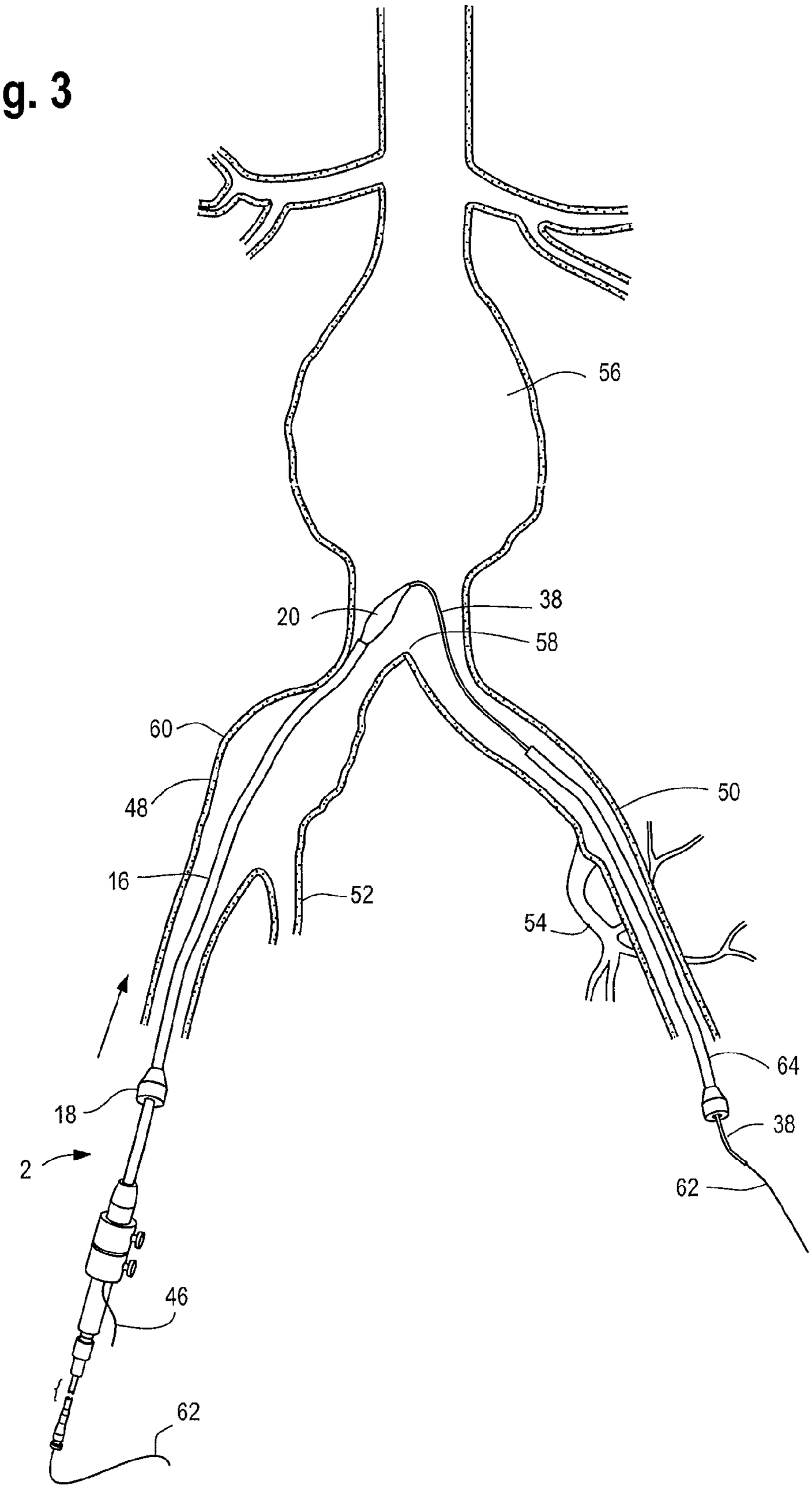


Fig. 4

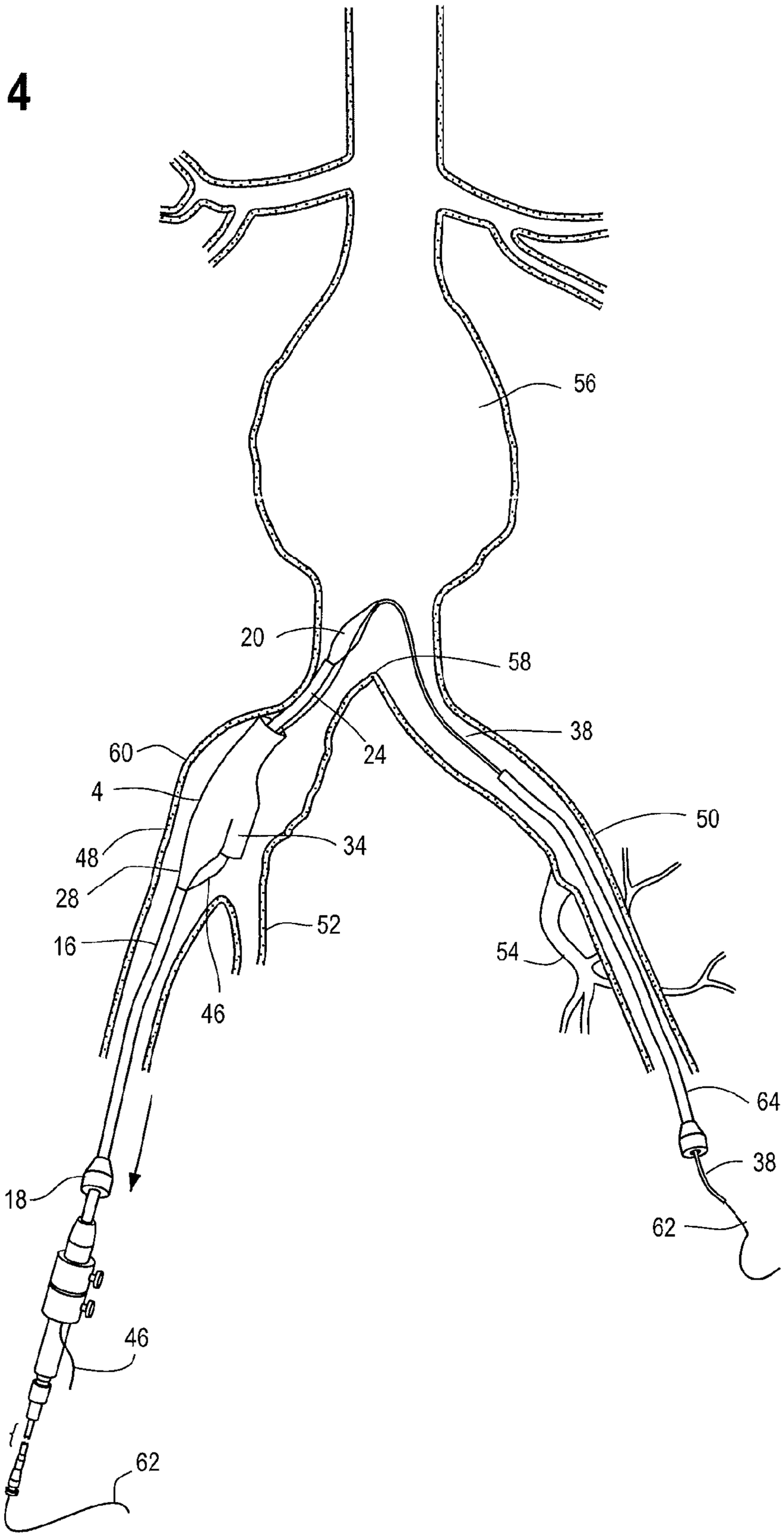
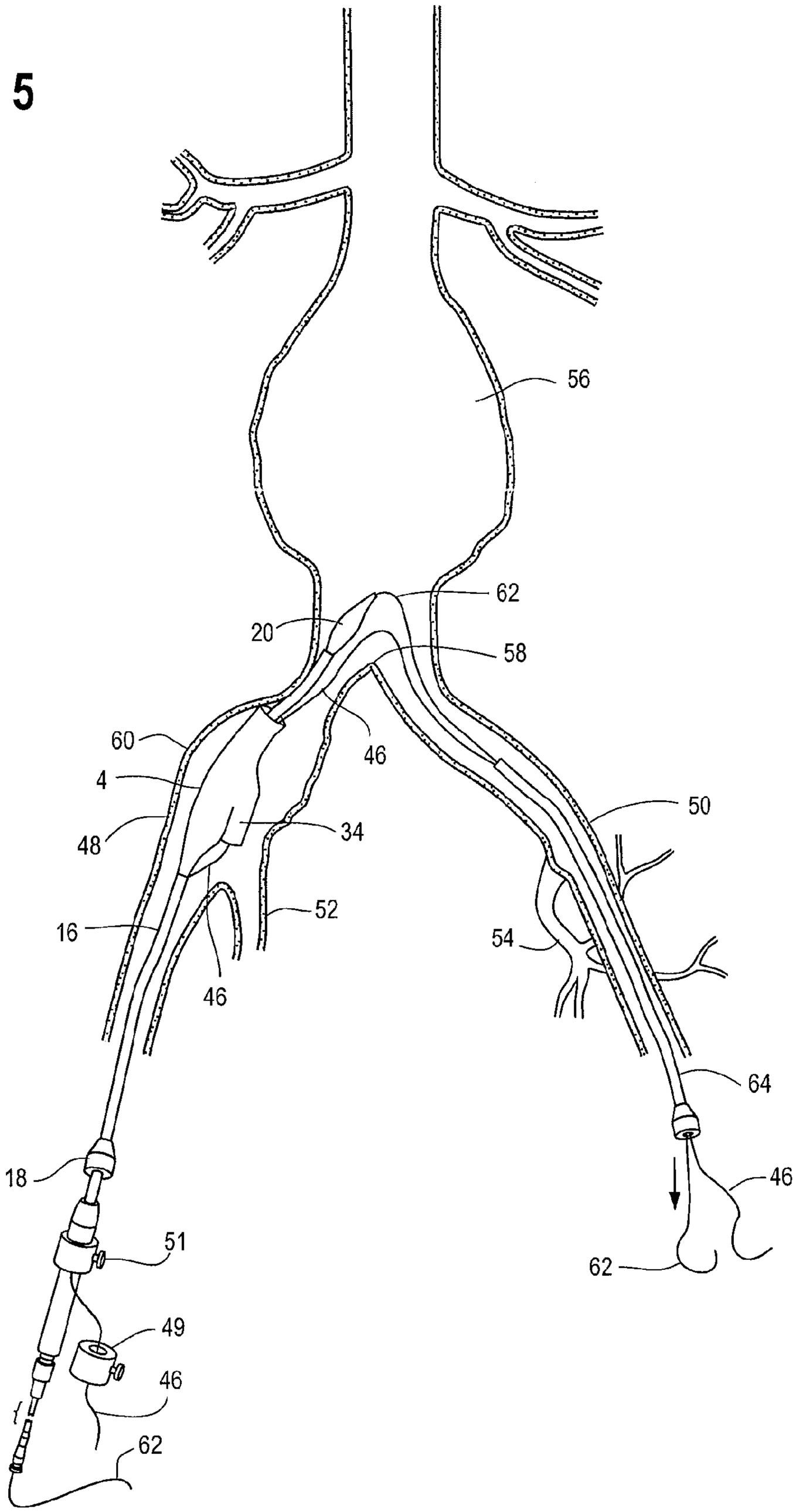


Fig. 5



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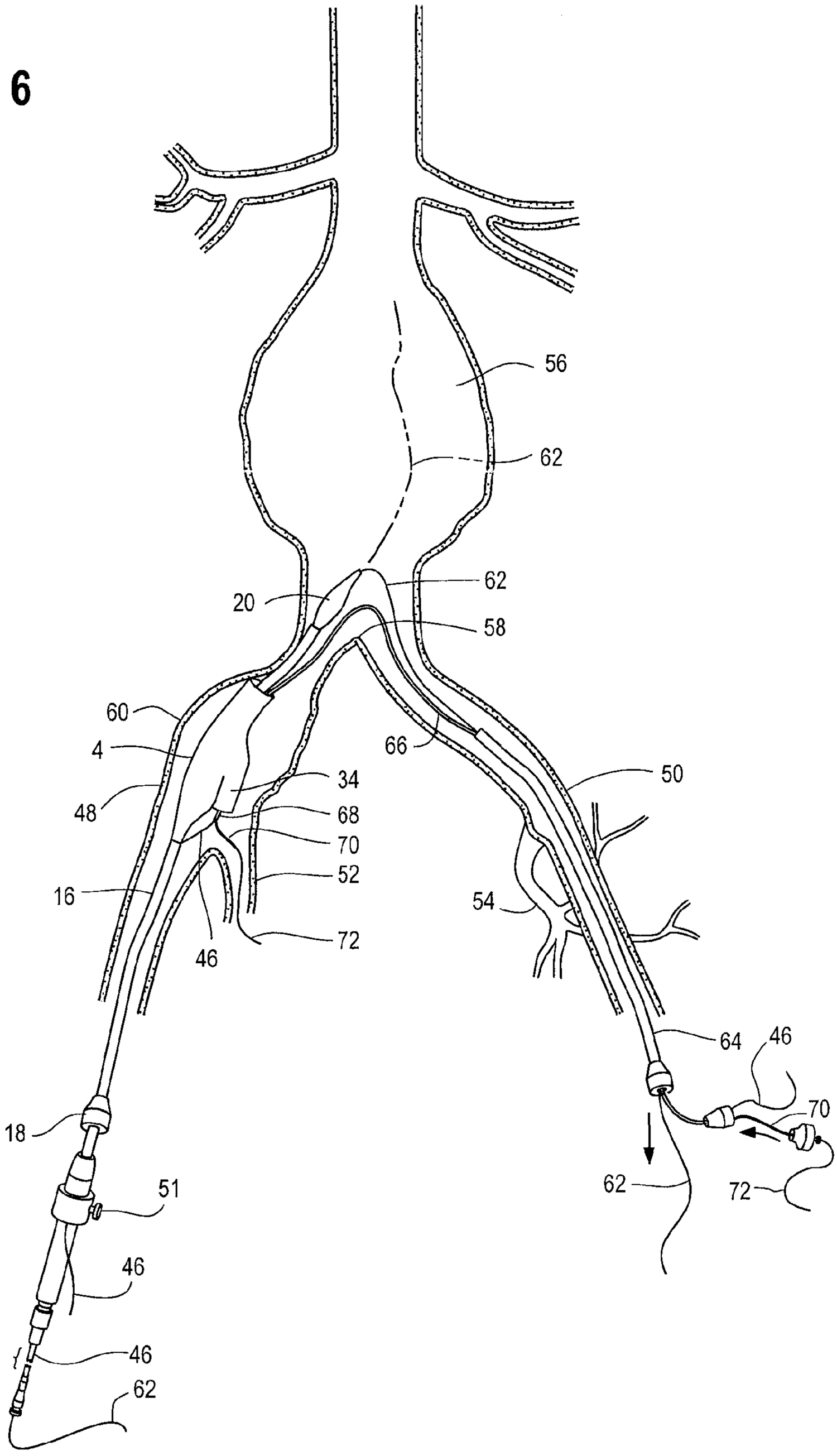
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Fig. 7

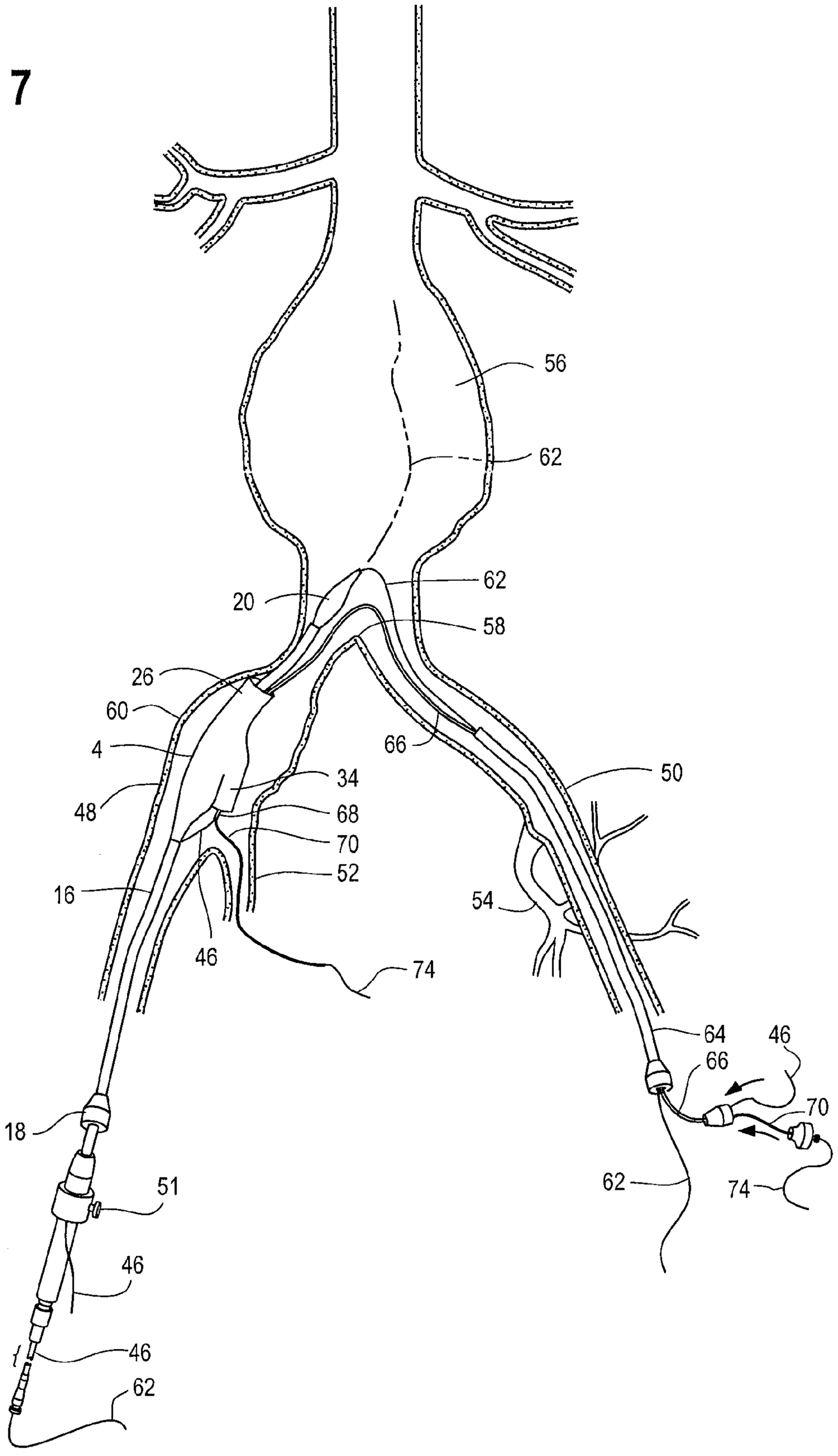
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Fig. 8

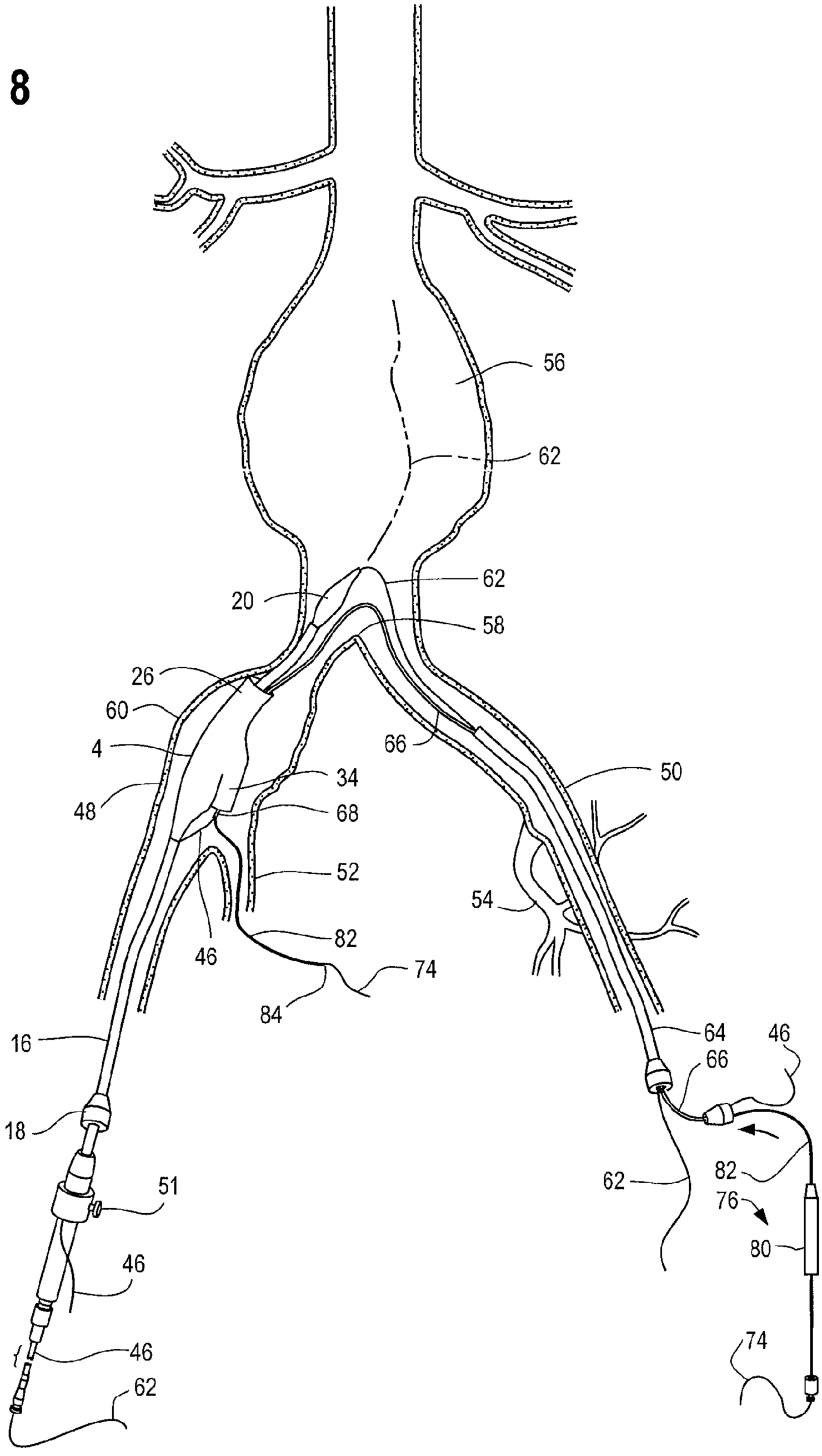
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Fig. 9

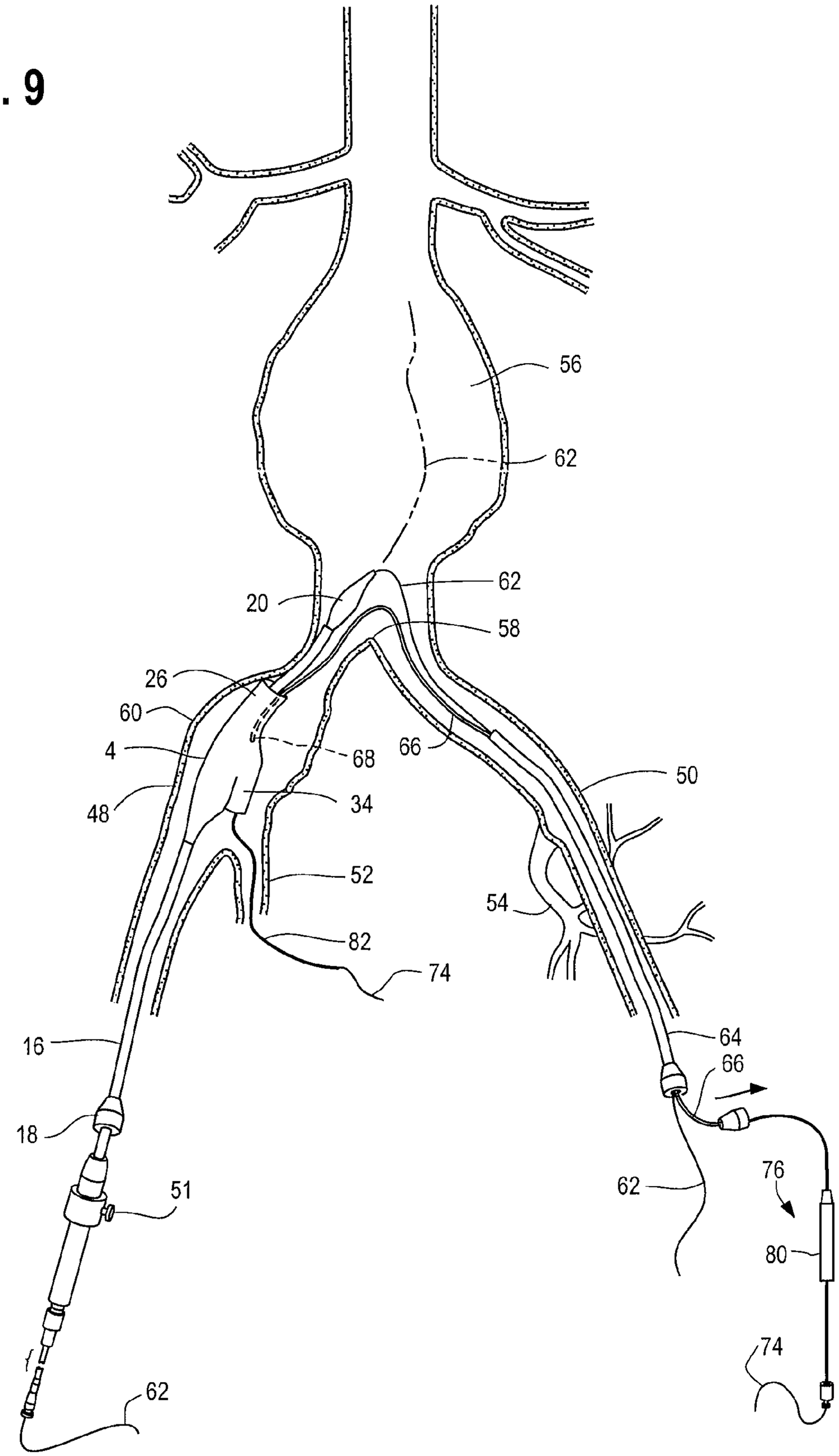
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Fig. 10

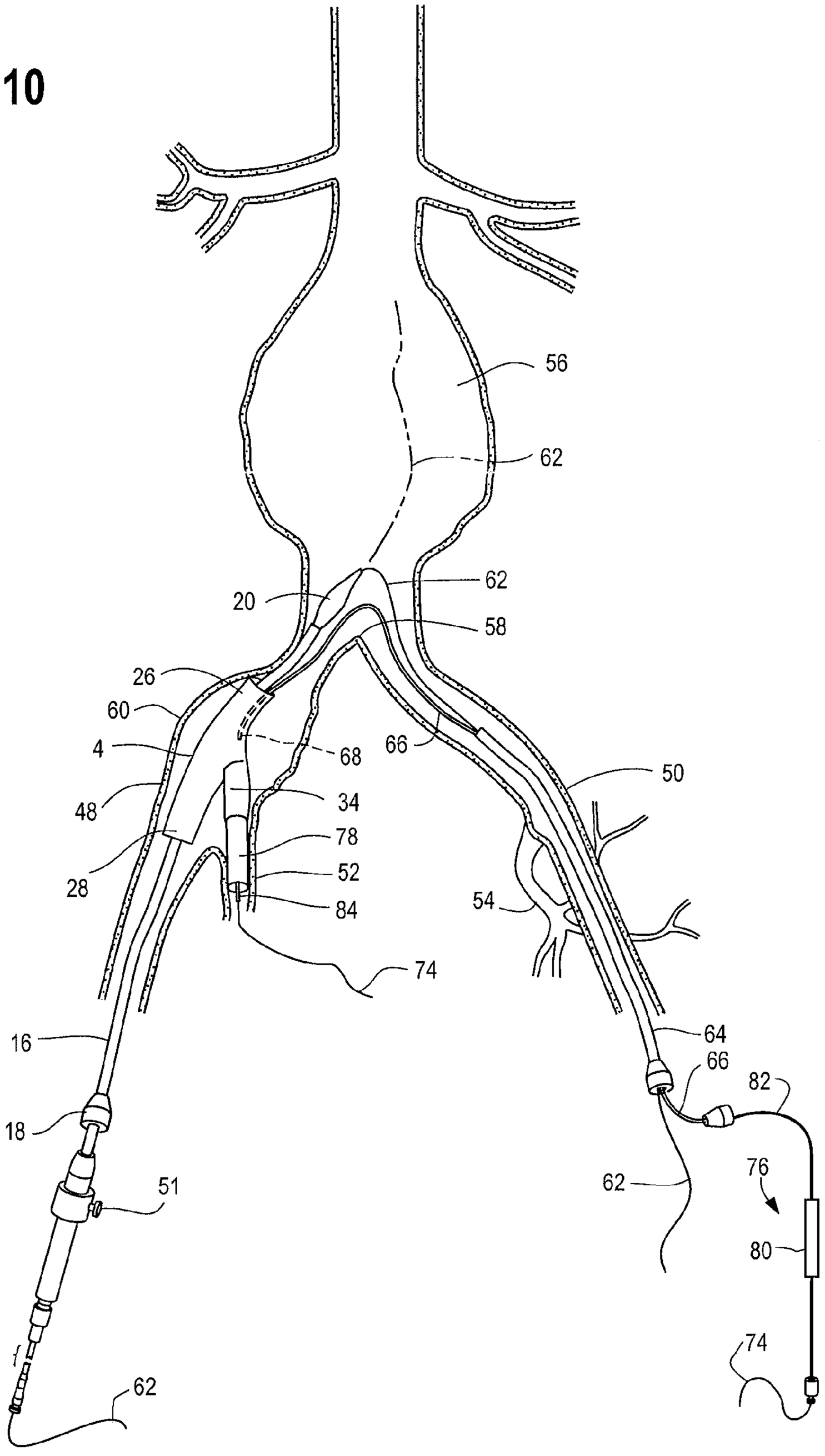
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Fig. 11

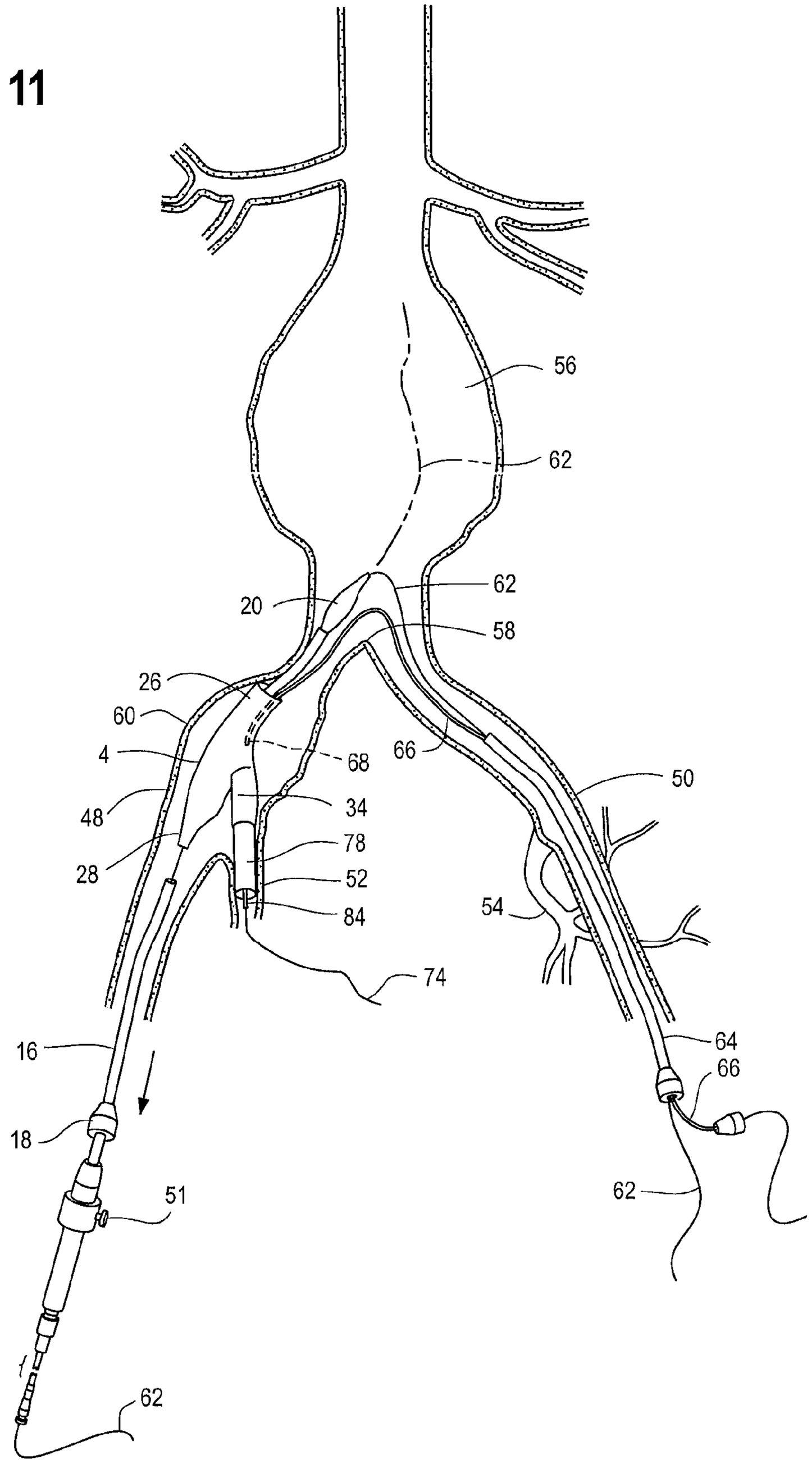
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Fig. 12

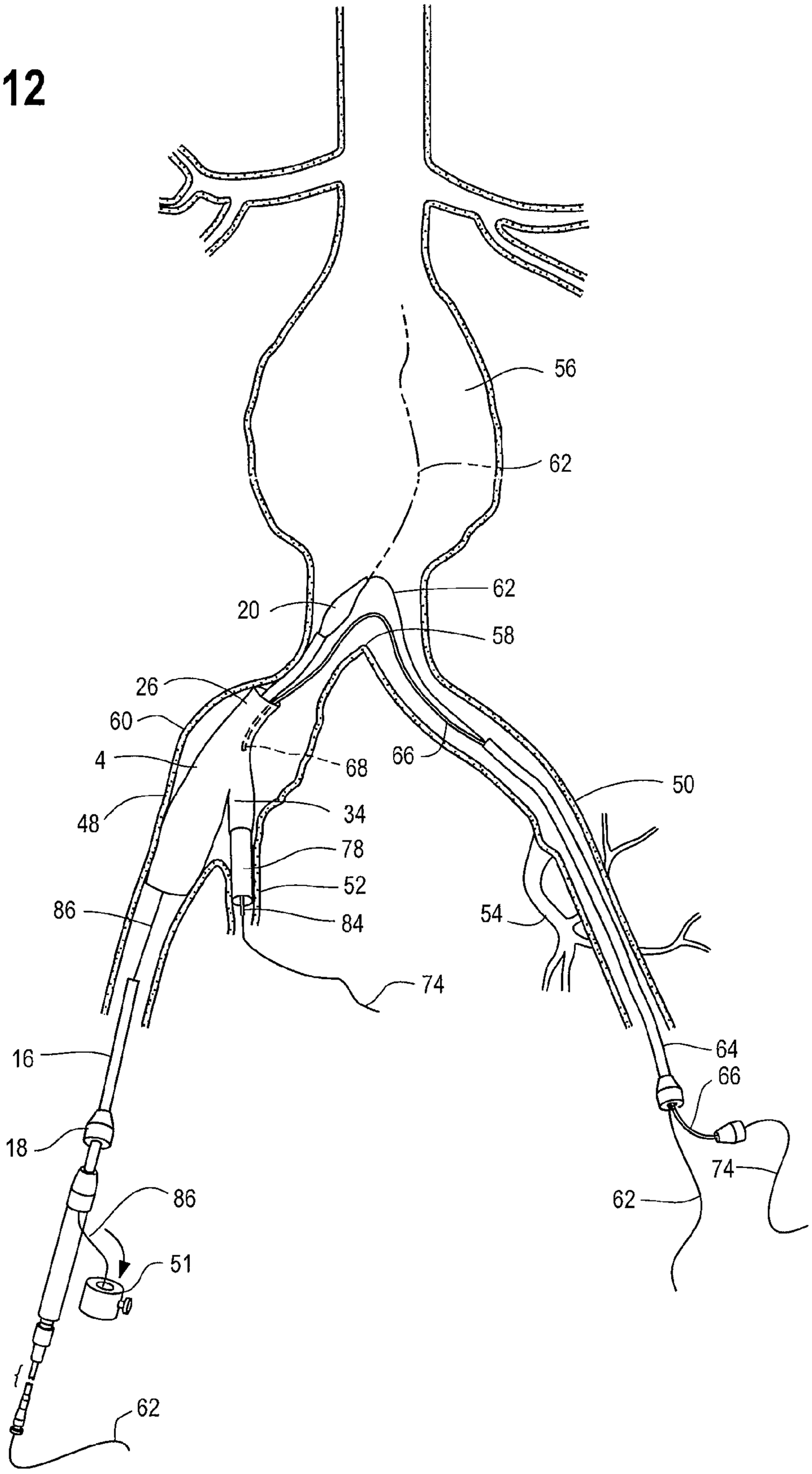
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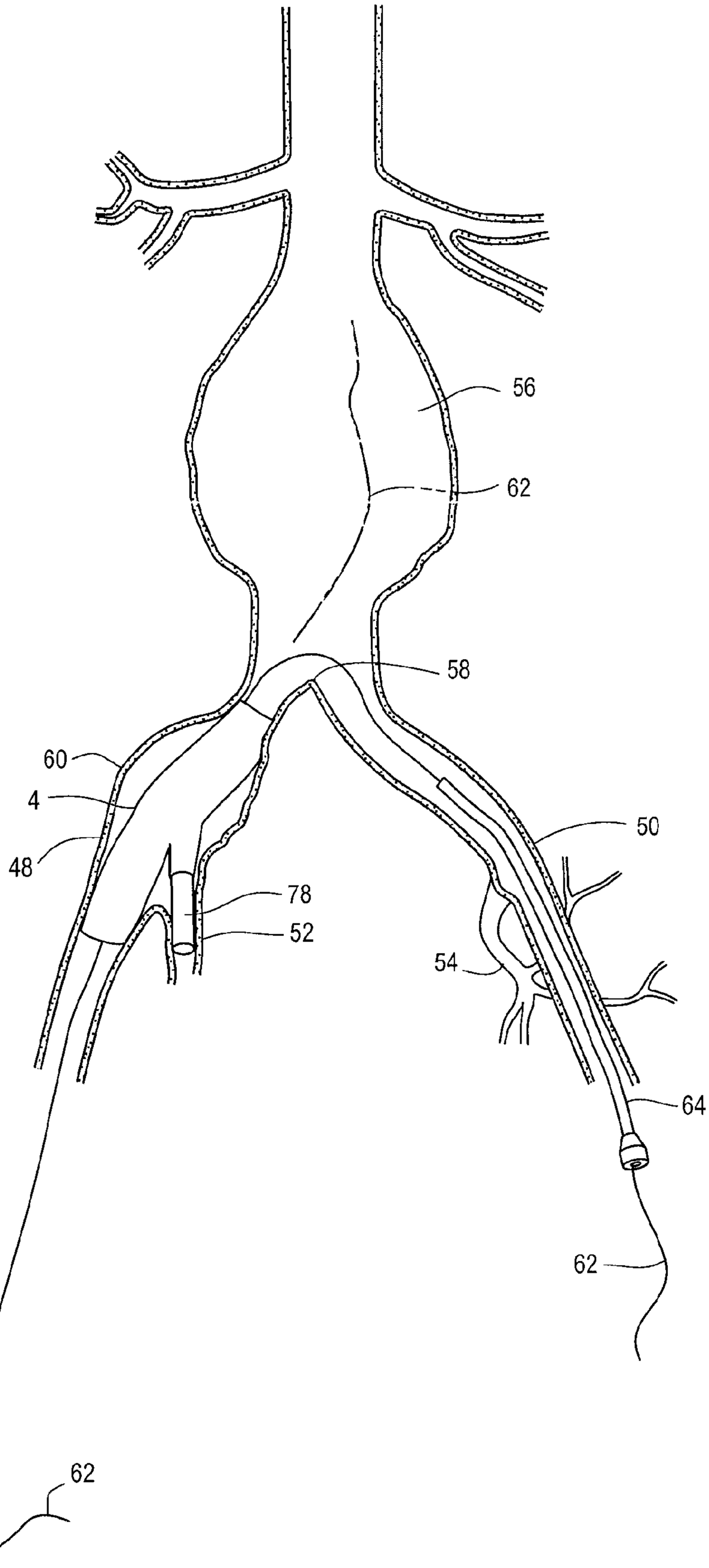
Fig. 13



EXTENSION FOR ILIAC BRANCH DELIVERY DEVICE AND METHODS OF USING THE SAME

BACKGROUND

This invention relates generally to medical devices and methods of using the same, and more particularly, to an endovascular stent graft delivery device and methods for placement and deployment of the graft in the lumen of a branched vessel such as an iliac artery.

Stent grafts may be inserted into an anatomical vessel or duct for various purposes. For example, stent grafts are used for treatment of vasculature in the human or animal body to bypass a repair or defect in the vasculature or to maintain or restore patency in a formerly blocked or constricted passageway. For example, a stent graft may extend proximally and/or distally away from a vascular defect, including a diseased portion of an aneurysm, and engage a healthy portion of a vessel wall. In many cases, however, such a damaged or defective portion of the vasculature may include a branched or side vessel such as a common iliac artery and/or an internal iliac artery extending from the common iliac artery. Commonly, to repair a defect in these branched vessels, a stent graft is provided which, when deployed in the common iliac artery, has a side branch or arm positioned towards the opening to the internal iliac artery and then, if desired, another stent graft can be deployed through the side branch into the internal iliac artery to bypass a diseased portion thereof and restore the blood flow path to the internal iliac artery.

Generally, when deploying an endovascular stent graft into a vessel lumen, it is possible to obtain access to such a lumen from one or both ends of the vessel where necessary, thereby facilitating placement of a graft in the desired portion of the lumen. However, the internal iliac artery, which extends from the common iliac artery below the aortic bifurcation, is a blind vessel because there is no practical way of performing a minimally invasive endovascular procedure into that vessel other than by entry from the common iliac artery.

Access to and introduction of a stent graft into the common and/or internal iliac arteries and successful deployment of a stent graft in such vessels may often depend upon a favorable layout of the arteries and, in many cases, access is difficult. One known approach that has been used includes accessing the target location(s) within the vessels by a contralateral or crossover approach. In other words, a delivery device having a guide wire carried thereon may be first introduced into a common iliac artery and the wire snared and pulled though the delivery device (while the device is still sheathed) from the contralateral side so that it extends across the aortic bifurcation. The wire is often covered by a catheter to allow manipulation of the wire during snaring. In this way, a pathway is created in the vasculature to facilitate the introduction and deployment of a stent graft to the target location in the contralateral internal iliac artery.

As endovascular techniques become more refined, physicians continue to seek novel alternative and simplified approaches to treating diseased vessels, including delivery devices that facilitate introduction and deployment of stent grafts into branched and/or blind vessels that are difficult to access and traverse. For example, accessing the target location(s) within the common and/or internal iliac artery using a low-profile delivery device for placing a stent graft in one or more branched vessels that eliminates the need to snare and pull a pre-loaded guide wire though the sheathed delivery device and over the aortic bifurcation is desirable. A method for introducing a stent graft into the common and/or internal iliac arteries and a delivery device to enable such a method to be practiced is described herein.

While this invention will be generally discussed in relation to a delivery device for a stent graft and method of deployment thereof into a common iliac artery where it is necessary to extend a side branch from a main portion or body of the graft into an internal iliac artery, it is also contemplated that the invention is not so limited and may relate to any body or vessel lumen in which such a deployment is necessary or desired.

SUMMARY

The present disclosure provides a system and method for delivering and deploying an endovascular graft into one or more branched vessels.

In one example, the system comprises a delivery device comprising a pusher catheter having a proximal end portion and a distal end portion and a lumen extending therebetween. A cannula having a proximal end portion and a distal end portion extends longitudinally within the lumen of the pusher catheter and a nose cone dilator is located proximal of the proximal end portion of the cannula. The nose cone may include a proximal tip. The device may further comprise an extension sheath extending from the proximal tip of the nose cone dilator, the sheath having a lumen extending therethrough. A stent graft may be carried on the delivery device. In one example, the stent graft may comprise a main tubular body of a biocompatible graft material defining a main lumen having a proximal end portion and a distal end portion, a side branch extending from the main tubular body, the side branch defining a lumen and being in fluid communication with the main lumen. The stent graft may be configured to be deployed into the vasculature of a patient with the main tubular body being located in the ipsilateral common iliac artery and the side branch being directed towards an internal iliac artery of the common iliac artery. The device may further comprise a pre-loaded guide wire extending through the lumen of the pusher catheter, through the side branch lumen and extend out of the proximal end portion of the main graft body. The guide wire may further extend at least partially through the lumen of the extension sheath.

The system may further comprise a second delivery device. In one example, the second delivery device comprises a second stent graft having a tubular body of biocompatible graft material defining a main lumen carried on a proximal end portion of the second delivery device.

A method for treating a diseased vessel is also described. In one example, the method comprises introducing a delivery device into an ipsilateral common iliac artery. The delivery device preferably comprises a pusher catheter having a proximal end portion and a distal end portion and a lumen extending therebetween, a cannula having a proximal end portion and a distal end portion extending longitudinally within the lumen of the pusher catheter, a nose cone dilator proximal of the proximal end portion of the cannula, an extension sheath extending from the proximal tip of the nose cone dilator, the sheath having a lumen extending therethrough. A stent graft comprising a main tubular body of a biocompatible graft material defining a main lumen having a proximal end portion and a distal end portion, a side branch extending from the main tubular body, the side branch defining a lumen and being in fluid communication with the main lumen, is carried on the delivery device. The stent graft

is configured to be deployed into the vasculature of a patient with the main tubular body being located in the ipsilateral common iliac artery and the side branch being directed towards an internal iliac artery of the common iliac artery. A pre-loaded guide wire extends through the lumen of the pusher catheter, through the side branch lumen and extends out of the proximal end portion of the main graft body. The pre-loaded guide wire has a proximal end portion extending at least partially through the lumen of the extension sheath. The method further comprises the step of extending the extension sheath and proximal end portion of the guide wire over the aortic bifurcation and in a distal direction down the contralateral common iliac artery. The method may further comprise the steps of at least partially deploying the stent graft in the ipsilateral common iliac artery and withdrawing the extension sheath from the patient's vasculature. In addition, the method may further comprise. The method of claim **11** further comprise introducing an auxiliary sheath having a lumen into the contralateral common iliac artery, tracking the auxiliary sheath over the pre-loaded guidewire such that the sheath lumen provides a pathway that extends from the contralateral common iliac artery, over the aortic bifurcation, through the proximal end portion of the main graft and through the lumen of the side branch. A second delivery device may be delivered through the pathway defined by the auxiliary sheath lumen, wherein the second delivery device comprises a second stent graft carried on a proximal end portion thereof, the second stent graft comprising a tubular body of a biocompatible graft material. The second stent graft may be positioned within the ipsilateral internal iliac artery and at least partially deployed therein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows one example of a pre-loaded delivery device for introducing, placing and deploying a stent graft into a patient's vasculature.

FIGS. **2-13** illustrate a portion of a patient's vasculature and an example of the various stages of the introduction, placement and deployment of a stent graft into a common iliac artery and an internal iliac artery.

DETAILED DESCRIPTION

Throughout this specification the terms "proximal" and "proximally" are used for a position or direction towards the patient's heart and the terms "distal" and "distally" are used for a position or direction away the patient's heart. The term "ipsilateral" is used to indicate that the diseased vessel(s) being accessed during a given procedure are on the same side of the body (right or left) as the vascular access device/introducer, while "contralateral" signifies that the vessel(s) of interest are on the opposite side of the body.

The embodiments described below are in connection with systems and methods for the introduction and deployment of an implantable medical device in a vessel, such as endovascular prosthesis, but could also be used for deploying a range of implantable medical devices including, but not limited to, stents, stent grafts, occlusion devices and the like.

Referring to FIG. **1**, an example of a stent graft delivery device is shown generally at **2** with a stent graft **4** mounted onto it. During the medical procedure to position and deploy the stent graft **4**, the proximal end **6** of the device **2** will travel through the vessel lumen to a desired deployment site. The distal external manipulation section **8** which may include a handle portion, which is acted upon by a user to manipulate the device, remains outside of the patient throughout the procedure. The delivery device **2** is preferably "pre-loaded", or in other words, before the delivery device is introduced into the patient's vasculature, it is pre-assembled with mechanisms that facilitate graft delivery and deployment already arranged thereon. The delivery and deployment mechanisms may include, for example, one or more guide wires, catheters, sheaths, stent grafts and combinations thereof, which are arranged on and/or are carried by the device **2** and which remain in place during delivery of the stent graft **4** into a patient's vasculature. In one non-limiting example, the delivery device **2** may include one or more mechanism that aid in the placement and deployment of a stent graft **4** in the common iliac artery and/or one or more mechanisms that aid in the placement and deployment of an additional or side branch extension stent grafts in an internal iliac artery in accordance with the systems and methods described herein.

More specifically, as shown in FIG. **1**, the device **2** includes a pusher catheter **10** having a proximal end portion **12** and a distal end portion **14**. In one example, the pusher catheter **10** has at least one lumen extending between the proximal **12** and distal **14** end portions. A sleeve or sheath **16**, which may be operated by a sheath manipulator **18**, is preferably mounted co-axially over the pusher catheter **10**. In the ready-to-deploy position, the sheath **16** extends proximally to the nose cone dilator **20** and covers a stent graft **4** carried on the device **2**. As illustrated in FIG. **1**, however, the sheath **16** is withdrawn so that the stent graft **4** is exposed to show detail of the assembly. A handle **22** at the distal end **14** of the pusher catheter **10** enables manipulation of various components of the device **2**.

As shown in FIG. **1**, a cannula **24** extends through the lumen of the pusher catheter **10**, from the distal end **8** of the device to immediately distal of the nose cone dilator **20**. A branched stent graft **4** may be retained on the device **2**, and, in one example, the proximal end of the graft **26** may be secured to the cannula **24** by a retention arrangement immediately distal of the nose cone dilator **20**. The branched stent graft **4** may also be retained at its distal end **28** by another retention arrangement on the device **2**. Retention may be by various means, and in one non-limiting example, may include one or more loops or stitches of suture material which are engaged with a trigger wire extending from an aperture (not shown) in the cannula **24**. In another example, a trigger wire (not shown) may pierce or be woven through the stent graft **4** directly, thus, retaining the graft against the cannula **24** until the trigger wire(s) is removed. However, it is also contemplated that other types and methods of proximal and/or distal restraint may be used including various diameter reducing ties, fasteners or the like that are suitable for removably securing the stent graft **4** on the device **2**. The retaining mechanisms may be placed in any suitable arrangement or location so that the graft **4** is removably secured to the device **2**. The proximal and/or distal ends of the stent graft **4** may be released from this retention arrangement by releasing the one or more mechanisms (i.e. releasing a suture and trigger wire or any other type of mechanisms that may be used in combination with or in place of such sutures) during deployment of the graft, thereby facilitating at least partial deployment of the stent graft **4** within a vessel lumen.

The stent graft **4** carried on the device **2** preferably has a substantially tubular main body **30** having a proximal end portion **26** and a distal end portion **28** with a main lumen **32** extending through the main tubular body **30**. A side branch **34**, also preferably having a substantially tubular body defining a lumen **36**, preferably extends from the main body

30 and may be integrally formed with the main body, or alternatively, the side branch **34** may be a separately formed component that is secured to the main body **30** such as by stitching, bonding, adhesive or the like. The lumen **32** of the main body and the lumen **36** of the side branch are preferably in fluid communication. In one example, both the main body **30** and the side branch **34** are constructed from of one or more biocompatible materials including, but not limited to, polyesters, fluorinated polymers and polyurethanes and/or may be made from natural or organic materials. The materials may also be subjected to surface modifications or coatings.

In a preferred example, the stent graft **4** is configured to be deployed into the vasculature of a patient with the main tubular body **30** being located in the common iliac artery and the side branch being directed towards an internal iliac artery of the common iliac artery, although other stent graft configurations for deployment into various other body vessels are also contemplated depending on various factors including, but not limited to the particular vessel(s) being treated and/or the location of a particular damaged or diseased portion of a vessel.

As shown in FIG. **1**, an extension sheath **38** extends from the proximal tip **40** of the nose cone dilator **20**. The extension sheath **38** is preferably flexible to allow it to be advanced through a patient's vasculature, and at least a portion of the extension sheath is, in one example, curved in a hook or U-shaped configuration. However, the extension sheath **38** may have a variety of shapes and configurations depending on the procedure being performed and the vasculature though which the delivery device is being navigated. A lumen **42** extends through the extension sheath **38**, and the sheath may terminate in a proximal tip **44**.

The delivery device **2** is preferably pre-loaded with a guide wire **46**. This pre-loaded guide wire **46** runs along the length of the delivery device and extends proximally from the proximal end **12** of the pusher catheter **10** and runs outside of the distal end portion **28** of the main graft body, and into the lumen **36** of the side branch **34**. The guide wire **46** continues to run proximally through the lumen **36** of the side branch **34**, out of the proximal end **26** of the main graft lumen **32** and, in a first "pre-deployment" position, the guide wire **46** extends through the lumen **42** of the extension sheath **38** and terminates at a location near the proximal tip **44** of the extension sheath **38**. In other words, the guide wire **46** is contained within the lumen **42** of the extension sheath **38** and conforms to the shape of the extension sheath as the sheath is introduced and advanced though a patient's vasculature. The guide wire **46** and the extension sheath **38** are separate components, however, such that the extension sheath **38** may be removed from a patient's vasculature at some point during a procedure while the guide wire **46** remains in place within the vasculature.

Looking to FIGS. **1** and **5**, the device also preferably includes one or more control mechanisms **49** located outside of the patient's body at the distal end portion **8** of the delivery device **2** which allows the physician to manipulate the extension sheath **38** and, at the appropriate time during a particular procedure, release the extension sheath **38** from the delivery device **2** so that the extension sheath can be removed from the vasculature as described herein. One or more additional control mechanisms, such as mechanism **51** which is also preferably located outside of the patient's body as shown in FIGS. **1** and **12**, can be acted upon by the physician to manipulate other components of the delivery device. In one non-limiting example, mechanism **51** may be connected to a distal end portion of one or more trigger wires or otherwise interface with the retention mechanism(s) that at least partially restrain and hold the stent graft **4** on the delivery device **2** prior to the final deployment of the graft **4** within the vessel lumen. Manipulation of control mechanism **51** preferably allows the removal of the trigger wire(s) and/or other retention mechanism(s) when it is appropriate or desirable to fully deploy the stent graft **4** in the vessel lumen during a particular procedure.

Now looking at FIGS. **2** through **13**, it will be seen that there is schematically illustrated a series of vessels within the human body, including the common iliac arteries **48** and **50** and the respective internal iliac arteries **52** and **54**. The systems and methods described herein find particular application in the delivery, placement and deployment of one or more stent grafts therein, although as discussed earlier, the disclosed systems and methods are not restricted to this particular purpose and may be used in a variety of applications as will be appreciated by one of skill in the art.

Turning to FIG. **2**, a descending aorta **56** extends down to an aortic bifurcation **58** from which extend common iliac arteries **48** and **50**. From each of the common iliac arteries an internal iliac artery **52** and **54**, respectively, extends. In most cases, the internal iliac arteries **52** and **54** cannot be practically accessed from their distal ends remote from the junction with the common iliac artery. For illustrative purposes, common iliac artery **48** is shown as having a diseased portion, including an aneurysm **60**, although, it will be appreciated that one or both common iliac arteries **48**, **50** and/or one or both internal iliac arteries **52**, **54** may also include diseased portions that may be treated in accordance with the systems and methods described herein.

As shown in FIG. **2**, the introduction of the delivery device **2** is preferably preceded by the placement of a "through wire" **62** within the vasculature of a patient, which provides an "up and over" pathway (i.e. a pathway extending proximally up through the contralateral iliac artery **50**, over the aortic bifurcation **58** and distally down the ipsilateral common iliac artery **48**). The pathway provided by the through wire **62** may be used to ultimately facilitate the introduction and placement of the delivery device **2** in a desired location with a vessel lumen, such as providing a pathway over which the delivery device **2** may be tracked or extended, for example.

The through wire **62** may be placed in the vasculature by various acceptable methods and techniques, and introduced through various locations. In one non-limiting example, the through wire **62** may be introduced into a femoral artery via a femoral incision (not shown) and extended proximally beyond the aortic bifurcation **58** to the descending aorta **56**. The wire may then be snared and pulled from the contralateral side to create the "up and over" pathway. Alternatively, the through wire **62** may be introduced into the vasculature through other locations, including, but not limited to through a brachial puncture (not shown) for placement in a desired location within the iliac arteries. As shown in FIG. **2**, a portion of the through wire extends through the lumen of an auxiliary sheath **64** that is positioned in the contralateral iliac artery **50**. Placement of the though wire **62** as shown in FIG. **2** by any number of acceptable techniques and methods aids in the introduction of the delivery device into the patient's vasculature as described in further detail below.

As shown in FIG. **3**, the device **2** may be introduced into the common iliac artery **48** and advanced over the through wire **62** with the nose cone dilator **20** located near the aortic bifurcation **58**. Preferably, the device is advanced so that the extension sheath **38**, with the preloaded guide wire **46**

enclosed within the lumen of the sheath **38**, extends over the aortic bifurcation **58** and is tracked distally through the contralateral iliac artery **50** and through the auxiliary sheath **64** that remains in place in the contralateral iliac artery **50**. At this stage, sheath **16**, extending proximally up to the nose cone dilator **20**, covers the branched stent graft **4** that is carried on the device **2**, so that the graft **4** is not visible in FIG. **3**. With the device **2** in this position within the lumen of common iliac artery **48**, the graft **4** (enclosed within the sheath **16**) is preferably adjacent to the opening of the internal iliac artery **52**.

As shown in FIG. **4**, the sheath **16** has been partially withdrawn (in a distal direction) to expose the branched stent graft **4** so that the sheath **16** is just distal of the distal end **28** of the graft **4**. The stent graft **4** is partially unconstrained in that it has been freed from the confines of the sheath **16**, but it is still preferably retained by a retention mechanism at one or both of the proximal **26** and distal **28** ends of the stent graft. The graft may also include constraints or diameter reducing ties in the central portion, if desired. Accordingly, the stent graft **4** is not yet in a fully expanded condition within the lumen of the common iliac artery **48**. It can be seen that the stent graft **4** carried on the device **2** is pre-loaded in one exemplary arrangement. More specifically, the device **2**, with the stent graft **4** carried thereon, is pre-loaded as described above in connection with FIG. **1** such that the pre-loaded wire **46** extends proximally through the pusher catheter **10**, through the lumen **36** of the side branch **34**, out of the proximal end **26** of the main graft body **4** and through the lumen **42** of the extension sheath **38**. However, it is also contemplated that the device can be pre-loaded in a variety of acceptable ways that may not only aid in the placement and deployment of the main stent graft **4** in the common iliac artery but which also ultimately facilitates the placement of one or more additional stent grafts into the branched vessels, including, but not limited to, the internal iliac artery.

FIG. **5** shows an example of the next stage a graft delivery and deployment sequence where the extension sheath **38** may be removed from the patient's vasculature. (Although, it is also contemplated that the steps illustrated in FIGS. **4** and **5** could be reversed, such that the extension sheath **38** may be removed before graft **4** is unsheathed.) In one example, the control mechanism **49** located outside of the patient's body at the distal end portion **8** of the delivery device **2** can be manipulated by the physician, such as to release the extension sheath **38** from the delivery device **2** so that the extension sheath can be separated from the device and removed from the vasculature. The extension sheath **38** may be withdrawn distally through the auxiliary sheath **64** (as shown by the arrow in FIG. **5**) from the contralateral iliac artery **50**, although, if desired or necessary, the extension sheath **38** may be withdrawn by other acceptable techniques and methods, and/or withdrawn through other locations. With the extension sheath **38** removed, the pre-loaded wire **46** preferably remains in place as shown in FIG. **5** such that it extends through the delivery device **2** (in the ipsilateral iliac artery **48**), out the proximal end **26** of the main graft body **4**, over the aortic bifurcation **58** and distally through the auxiliary sheath **64** (in the contralateral iliac artery **50**).

In the example described above, at this stage, the pathway provided by the pre-loaded guide wire **46** is essentially parallel to the "up and over" pathway provided by the through wire **62**, and as shown in FIG. **5**, both the pre-loaded wire **46** and the through wire **62** each have terminal ends that can preferably be accessed on the outside of a patient's body on one or both of the ipsilateral and/or contralateral sides **48**, **50**. Wire **46** may allow a physician to introduce, manipulate and place a stent graft at a desired location within the patient's vasculature, such as in a common iliac artery, while control of both wires **46**, **62** may assist in the introduction of additional stent grafts in a branched and/or side vessel.

At this stage, an additional or "contralateral" sheath **66** is introduced into the patient's vasculature, which is preferably intended to facilitate the delivery and deployment of an extension graft into the ipsilateral internal iliac artery **52**. Alternatively, sheath **64** may be used instead of using an additional sheath **66** if sheath **64** has the appropriate properties, including, but not limited to being larger than the extension sheath that is introduced therethrough (as described in detail below) and is long enough to reach the contralateral iliac artery **50**.

As illustrated in FIG. **6**, a contralateral sheath **66** may be extended proximally through the contralateral iliac artery **50**, over the aortic bifurcation **58**, into the proximal end **26** of the main graft body **4** and through the lumen **36** of side branch **34**. This may be accomplished by tracking the contralateral sheath **66** through the lumen of the auxiliary sheath **64** and over the pathway provided by the pre-loaded guide wire **46** (shown in FIG. **5**) which is still in place in the iliac arteries **48**, **50**. As FIG. **6** best shows, the contralateral sheath **66** is extended until the tip **68** of the sheath **66** emerges from the distal end of the side branch **34** such that the tip **68** adjacent to the opening of the internal iliac artery **52**. Alternatively, as FIG. **6** illustrates, the original through-wire **62** may be pulled in a proximal direction and advanced up into the infrarenal aorta **56**, as shown by the dashed line in FIG. **6**. With wire **62** extending proximally into the aorta **56** rather than distally through the contralateral sheath **66** (in contralateral iliac artery **50**), space is freed up in the auxiliary sheath **64** (which would otherwise be taken up by the wire **62**) to make room in the sheath **64** for the contralateral sheath **66** and auxiliary catheter **70** to be advanced therethrough.

Auxiliary catheter **70**, with an auxiliary wire **72** extending longitudinally through the lumen thereof, may be advanced all the way through the contralateral sheath **66** for cannulation of the internal iliac artery **52**, as shown in FIG. **6**.

The original auxiliary wire **72** that extends through auxiliary catheter **70** and that is initially introduced into the internal iliac artery **52** (as shown in FIG. **6**) may be replaced with an alternative, stiffer auxiliary wire **74**, if desired, which may be extended further, along with the auxiliary catheter **70**, into the internal iliac artery **52**, as illustrated in FIG. **7**.

With the stiffer auxiliary wire **74** extended into and placed in a desired location in the internal iliac artery **52**, the auxiliary catheter **70** can be withdrawn from the patient's vasculature as shown in FIG. **8**. In one example, the auxiliary catheter **70** can be pulled distally through the contralateral sheath **66** (through the contralateral iliac artery **50**) and removed from the vessel. The auxiliary wire **74** remains in place, however, after the auxiliary catheter **70** has been removed from the patient's body. At this stage, a second delivery device **76** can be tracked over the pathway provided by the auxiliary wire **74**. The second delivery device **76** preferably carries an additional leg or "extension" stent graft **78** that is intended for delivery and deployment within the internal iliac artery **52**, although extension graft **78** may be deployed within any portion of the patient's vasculature as necessary or desired. The extension graft **78** is preferably carried on a proximal end portion of the second delivery device **76**, while a distal external manipulation portion **80** remains outside of the patient's body and allows a physician

to manipulate the second delivery device **76** within the patient's vasculature. The extension graft **78** is preferably covered by an appropriately sized sheath **82** (so that the extension graft **78** is not visible in FIG. **8**). The second delivery device **76** is tracked over the auxiliary wire **74** until the proximal end portion or tip **84** of the device **76** is extended beyond tip **68** of the contralateral sheath **66**, into the internal iliac artery **52**, and the extension graft **78** positioned in a desired location therein. Preferably, the extension graft **78** is positioned in the internal iliac artery **52** so that it extends both proximally and distally away from the location of an aneurysm, therefore, spanning and bypassing the diseased portion of the vessel.

At this stage, the contralateral sheath **66** can be partially withdrawn, as shown in FIG. **9**. In one example, the contralateral sheath **66** may be pulled distally from the contralateral side **50** until the tip **68** of the contralateral sheath **66** is located approximately adjacent to the proximal end portion of the side branch **34**. At this time, the pre-loaded wire **46** may also be removed from the patient's vasculature. Preferably, this may be accomplished by pulling the pre-loaded wire **46** distally through the contralateral sheath **66** (within the lumen of the contralateral common iliac artery **50**) and out of the patient's body. However, the pre-loaded wire **46** may also be removed in other suitable ways including through the delivery device **2** on the ipsilateral side **48**.

As shown in FIG. **10**, the stent graft **4** and/or the extension graft **78** may be deployed within the lumen of the internal **52** and common iliac **48** arteries, respectively. For example, the sheath **82** covering the extension graft **78** on the second delivery device **76** may be withdrawn by pulling the sheath **82** distally through the contralateral sheath **66** for removal from the patient. At this time, the second delivery device **76** may also be removed from the patient's vasculature by pulling the second delivery device **76** distally through the contralateral sheath **66** (within the common iliac artery **50**). In addition, the main sheath **16** (which covered the main stent graft **4** prior to delivery and deployment) may be withdrawn by pulling the sheath **16** distally from the ipsilateral common iliac artery **48** as shown in FIG. **11**. After removal of the main sheath **16** from the main graft **4** and the extension sheath **82** from the extension graft **78**, the grafts **4**, **78** are at least partially deployed within the vessels **48**, **52**. To fully deploy the main **4** and extension grafts **78**, the retention mechanism(s) that releasably retain the proximal end **26**, the distal end **28** (or both ends) of the stent graft **4** on the delivery device **2**, if present, are preferably removed.

To accomplish removal of the retention mechanism(s) when it is appropriate or desirable to fully deploy the stent graft **4** in the vessel lumen **48** during a particular procedure, the additional control mechanism **51** as shown in FIG. **12** for example, can be acted upon by the physician to manipulate and remove one of the trigger wire(s) **86** and/or other retention mechanism(s). Once the retention mechanism(s) (not shown) have been removed from the proximal **26** and/or distal ends **28** of the stent graft **4** (and/or from extension graft **78** if such retention mechanisms are present in the second delivery device **76**), the respective grafts **4**, **78** may be radially expanded or deployed within the respective vessels **48**, **52**.

In one example, a "self-expanding" stent expands primarily based on its own expansive force without the need for further mechanical expansion. More particularly, a stent made of a shape-memory alloy such as Nitinol may allow the stent graft **4**, **78** to return to a predetermined expanded configuration upon removal of a sheath (e.g., sheath **16** or **82**) or other mechanism that maintains the stent graft **4**, **78** in its compressed, pre-deployment configuration. In another example, stents made of materials such as stainless steel may expand on their own accord once released from constraints holding them in their compressed state. Alternatively, a stent graft **4**, **78** may require further manipulation, mechanical or manual expansion, such as by balloon expansion by the user. In either case, it is contemplated that the stent graft **4**, **78** may expand or deploy only partially within the vessel lumen after removal of any retention mechanisms, such that additional expansion of the stent graft **4**, **78** may be desired or required, at which time the user may implement various known and acceptable techniques to fully deploy the graft **4**, **78** in the common **48** and/or branched vessel **52**. Such fully deployed stent grafts **4** and **78** are illustrated in exemplary FIG. **13**.

As shown in FIG. **13**, the leg extension graft **78** preferably extends from the side branch **34** of the stent graft **4** into the internal iliac artery **52**. Proximal and/or distal retention (not shown) of graft **78** may include the same or similar retention mechanisms as those described above in connection with the retention of stent graft **4** on delivery device **2**, such that graft **78** may be retained on the second delivery device **76** in a manner similar to that of graft **4**. Of course, other types and methods of proximal and/or distal restraint of extension graft **78** may be used including various diameter reducing ties, fasteners or the like that are suitable for removably securing the extension graft **78** on the further delivery device **76**. Proximal and/or distal retention of extension graft **78** may be in addition to or in combination with sheath **82** which also secures the graft **78** to second delivery device **76** and holds it in a radially inwardly compressed "pre-deployment" condition.

Following graft deployment, the delivery device **2** can also be withdrawn from the patient's body, if desired, although in some situations, it may be desirable to leave one or more components, such as pusher catheter **10** and/or the sheath **16** in position within the common iliac artery **48** so that further introduction and deployment of another stent graft into the aorta **56**, such as a bifurcated stent graft, can be facilitated through the pusher **10** and/or sheath **16**.

Thus, the pre-loaded delivery device with an extension sheath as described herein effectively and efficiently facilitates the introduction, placement and deployment of a stent graft into one or more branched vessels, including, but not limited to a common iliac artery and an internal iliac artery extending therefrom, in order to treat and/or restore patency to one or both of such vessels.

Throughout this specification, unless the context requires otherwise, the words "comprise" and "include" and variations such as "comprising" and "including" will be understood to imply the inclusion of an item or group of items, but not the exclusion of any other item or group items.

While various examples of the invention have been described, it will be apparent to those of ordinary skill in the art that many more examples and implementations are possible within the scope of the invention. Furthermore, although various indications have been given as to the scope of this invention, the invention is not limited to any one of these but may reside in two or more of these combined together. Accordingly, the invention is not to be restricted except in light of the attached claims and their equivalents.

The invention claimed is:

1. A system for the delivery and deployment of an endovascular graft comprising:

a. a delivery device comprising:

i. a pusher catheter having a proximal end portion a distal end portion and a lumen extending there between, and a proximal end opening;

ii. a cannula having a proximal end portion and a distal end portion extending longitudinally within the lumen of the pusher catheter;

iii. a nose cone dilator proximal of the proximal end portion of the cannula, the nose cone dilator having a proximal tip;

iv. an extension sheath extending from the proximal tip of the nose cone dilator, the extension sheath having a lumen extending there through, wherein a portion of the extension sheath has a U-shaped configuration;

b. a stent graft carried on the delivery device, the stent graft comprising:

i. a main tubular body of a biocompatible graft material defining a main lumen having a proximal end portion, a distal end portion, a distal end opening;

ii. a side branch extending from the main tubular body, the side branch defining a lumen and being in fluid communication with the main lumen, whereby the stent graft is configured to be deployed into the vasculature of a patient with the main tubular body being located in the ipsilateral common iliac artery and the side branch being directed towards an internal iliac artery of the common iliac artery;

c. a pre-loaded guide wire extending through the lumen of the pusher catheter, exiting the proximal end opening of the pusher catheter distal to the distal end opening of the main tubular body, extending entirely outside of the distal portion of the main tubular body along side the main tubular body and entering the main lumen of the main tubular body through the lumen of the side branch and extending out of the proximal end portion of the main tubular body, the pre-loaded guide wire further extending at least partially through the lumen of the extension sheath.

2. The system of claim **1** wherein the extension sheath is flexible and adapted to be manipulated though the contours of a vessel lumen.

3. The system of claim **1** wherein the stent graft is secured to the proximal end portion of the cannula.

4. The system of claim **1** wherein the delivery device further comprises a mechanism for manipulating the extension sheath.

5. The system of claim **1** further comprising a second delivery device, the second delivery device comprising a second stent graft carried on a proximal end portion of the second delivery device, the second stent graft comprising a tubular body of a biocompatible graft material defining a main lumen.

6. The system of claim **5** wherein the second delivery device is sized and configured to be advanced through the proximal end portion of the main tubular graft body and into the lumen of the side branch.

7. The system of claim **5** wherein the second stent graft carried by the second delivery device is configured to be positioned within the internal iliac artery.

8. The system of claim **5** further comprising a sheath mounted coaxially over at least a portion of the second stent graft.

9. The system of claim **1**, wherein the greatest diameter of the extension sheath is less than the diameter of the proximal tip of the nose cone dilator.

10. A method for treating a diseased vessel, the method comprising:

a. introducing a delivery device into an ipsilateral common iliac artery, the delivery device comprising:

i. a pusher catheter having a proximal end portion, a distal end portion and a lumen extending there between, and a proximal end opening;

ii. a cannula having a proximal end portion and a distal end portion extending longitudinally within the lumen of the pusher catheter;

iii. a nose cone dilator proximal of the proximal end portion of the cannula, the nose cone dilator having a proximal tip;

iv. an extension sheath extending from the proximal tip of the nose cone dilator, the extension sheath having a lumen extending there through, wherein a portion of the extension sheath has a U-shaped configuration;

v. a stent graft carried on the delivery device, the stent graft comprising a main tubular body of a biocompatible graft material defining a main lumen having a proximal end portion, a distal end portion, a distal end opening, a side branch extending from the main tubular body, the side branch defining a lumen and being in fluid communication with the main lumen, whereby the stent graft is configured to be deployed into the vasculature of a patient with the main tubular body being located in the ipsilateral common iliac artery and the side branch being directed towards an internal iliac artery of the common iliac artery;

vi. a pre-loaded guide wire extending through the lumen of the pusher catheter, exiting the proximal end opening of the pusher catheter distal to the distal end opening of the main tubular body, extending entirely outside of the distal portion of the main tubular body along side the main tubular body and entering the main lumen of the main tubular body through the side branch lumen and extending out of the proximal end portion of the main tubular body, the pre-loaded guide wire having a proximal end portion extending at least partially through the lumen of the extension sheath,

b. extending the extension sheath and proximal end portion of the pre-loaded guide wire over the aortic bifurcation and in a distal direction down the contralateral common iliac artery.

11. The method of claim **10** further comprising at least partially deploying the stent graft in the ipsilateral common iliac artery.

12. The method of claim **11** further comprising withdrawing the extension sheath from the patient's vasculature.

13. The method of claim **12** wherein the extension sheath is withdrawn from the contralateral side.

14. The method of claim **11** further comprising:

a. introducing an auxiliary sheath having a lumen into the contralateral common iliac artery, and

b. tracking the auxiliary sheath over the pre-loaded guidewire such that the sheath lumen provides a pathway that extends from the contralateral common iliac artery, over the aortic bifurcation, through the proximal end portion of the main graft and through the lumen of the side branch.

15. The method of claim 14 further comprising:

a. introducing a second delivery device through the pathway defined by the auxiliary sheath lumen, the second delivery device comprising a second stent graft carried on a proximal end portion thereof, the second stent graft comprising a tubular body of biocompatible graft material,

b. positioning, the second stent graft within the ipsilateral internal iliac artery,

c. at least partially deploying the second stent graft in the ipsilateral internal iliac artery.

16. The method of claim 15 further comprising removing the auxiliary sheath and second delivery device from the patient's vasculature.

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